K090783

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510(k) Summary

Submitter: Tuttnauer USA Co. Ltd.
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AUG 20 2009

Contact Name: Robert R. Basile, V.P.

Date Prepared: March 19, 2009

Common Name: Electronic pre-vacuum autoclave, steam sterilizer

Trade Name: Tuttnauer ELARA-11" Pre-vacuum Tabletop Autoclave

Classification Name: Steam Sterilizer
Class II Device – 21 C.F.R. § 880.6880

Substantial Equivalence:

The ELARA-11" is claimed to be substantially equivalent to the autoclaves cleared under K063711. Like these autoclaves, the ELARA-11" contains an electronic control panel that permits automatic usage, and it contains identical software to the autoclaves cleared under K063711. The ELARA-11" is a smaller model than the models to which substantial equivalence is claimed (*i.e.*, it is designed for a countertop). The nominal parameters (*e.g.*, sterilization temperature and time; dry time; and maximum/average cycle times) are also different for the ELARA-11" than for the devices under K063711; however, all devices use steam as the sterilization agent.

General Description:

The automated Tuttnauer ELARA-11" is a table-top steam sterilizer (*i.e.*, autoclave) designed for sterilizing medical and surgical goods, including both wrapped and unwrapped, solid, hollow, and porous products and goods defined as hollow A (*e.g.*, dental hand pieces; suction pipes) in ophthalmic, dental, and medical clinics; in first aid rooms; and in small laboratories. This device is a pre-vacuum and post-vacuum sterilizer that has an air removal stage (*i.e.*, pre-vacuum) before the start of the sterilization stage, as well as a post-sterilization drying stage that is based upon the combined operation of heat plus vacuum with air inlet pulses. The sterilizing agent is steam that is electrically-generated from either mineral-free or distilled water that is added to the built-in reservoir.

Only United States Food and Drug Administration cleared accessories such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes should be used with this autoclave. Sterilization programs 1, 2, 3, 4, and 5 are not considered by the Food and Drug Administration to be standard sterilization cycles. There are currently no sterilization wraps, sterilization pouches, chemical indicators, biological indicators, or sterilization cassettes cleared for use by the Food and Drug Administration for the specific sterilization parameters of sterilizer programs 1, 2, 3, 4, or 5.

Design and Materials:

The ELARA-11" is a steam sterilizer composed of a pressure vessel with steam jacket, heating elements, a clean water reservoir, a waste water reservoir, a vacuum pump, and a water pump. The device has several safety features, including an automated safety door with a double-safety locking mechanism and an automatic safety shutoff. The front panel of the device consists of a display screen, a keypad, and a printer. The ELARA-11" electronic control system is automatic, fully-configurable, and has a total of seven (7) programs: five (5) sterilization programs and two (2) test programs (Bowie & Dick test program with fixed (non-adjustable) parameters, and the VacTest program). The components are made of varying grades of stainless steel.

Comparison to Cleared Devices:

Although the ELARA-11" and the six (6) models cleared under K063711 differ in device size and program cycles, they all operate with an electronic control panel that permits automated usage, and all models utilize the same operational software. Furthermore, they all use steam as the sterilization agent.

Indications for Use: The ELARA-11" is a table-top autoclave designed for sterilizing medical and surgical goods, including both wrapped and unwrapped, solid, hollow, and porous products and goods defined as hollow A (*e.g.*, dental hand pieces; suction pipes) in ophthalmic, dental, and medical clinics; in first aid rooms; and in small laboratories.

Key program features, including cycle times, temperature, maximum load sizes, and recommended use of each program are listed in the following chart:

ELARA-11"
(sterilization chamber volume = 28.5 liters (7.5 gal))

Program	Recommended Use	Maximum Load (kg/lbs)	Sterilization Temperature (°C/°F)	Sterilization Time (minutes)	Dry Time	Max. Cycle Time	Ave. Cycle Time
1 (Flash 134)	unwrapped instruments	solid - 8/17.6	134/273	4	1	25	15
2 (WDry 134)	double-wrapped	solid - 8/17.6	134/273	4	20	50	42

	instruments, wrapped porous and hollow A loads	porous - 2/4.4					
3 (NoDry 121)	unwrapped instruments	solid - 8/17.6	121/250	20	--	40	35
4 (WDry 121)	double-wrapped instruments, wrapped porous and hollow A loads	solid - 8/17.6 porous - 2/4.4	121/250	20	20	70	60
5 (Delicate 121)	delicate instruments (porous wrapped and hollow A)	solid - 8/17.6	121/250	20	--	55	45
Test 1 (Bowie & Dick)	--	--	134 C	3.5	1	30	25
Test 2 (VacTest)	Cycle time – 20 min						

Technology:

The ELARA-11" is a steam sterilizer composed of a pressure vessel with steam jacket, heating elements, a clean water reservoir, a waste water reservoir, a vacuum pump, and a water pump. It contains an electronic control system that makes the device automatic and fully-configurable.

Non-Clinical Testing:

Tuttnauer conducted validation studies in accordance with AAMI/ANSI ST55:2003. Testing shows that the ELARA-11" meets all aspects of the standard, including physical and microbiological performance requirements.

Conclusion:

For all of the foregoing reasons, Tuttnauer believes that the ELARA-11" autoclave model described in this 510(k) notification may be safely marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

AUG 20 2009

Tuttnauer USA Company, Limited
C/O Mr. Theodore Sullivan
Buchanan Ingersoll and Rooney, LLP
1700 K Street, N.W., Suite 300
Washington, District of Columbia 20006

Re: K090783
Trade/Device Name: Tuttnauer ELARA-11" Pre-Vacuum Tabletop Autoclave
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: July 24, 2009
Received: July 28, 2009

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: _____

Device Name: Tuttnauer ELARA-11" Pre-vacuum Tabletop Autoclave

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Test 1 (Bowie & Dick)	--	--	134 C	3.5	1	30	25
Test 2 (VacTest)	Cycle time – 20 min						

Prescription Use ____ AND/OR Over-the-Counter Use _X_
(21 C.F.R. 801 Subpart D) (21 C.F.R. 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila N Murphy M.D.

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090783